

National and Sub-National Policy for Domestic Manufacturing Flexibility: A Policy Framework to Incentivize Flexibility Based on Lessons from the COVID-19 Medical Supply Response

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1. Introduction

In contexts where private incentives are insufficient to ensure national security, economic security, or social welfare (such as health), governments may need to act to ensure access to particular products. Traditional tools used by governments include stockpiling, supporting nationally-owned manufacturers, and procurement (including leveraging legislative authority such as the US Defense Production Act - DPA). These conventional tools, however, have limitations, in that a government could end up stockpiling or ensuring domestic manufacturers for products not suited to a specific crisis. Since 2020, the US market alone has seen medical supply shortages [\[source\]](#), semiconductor chip shortages [\[source\]](#), and baby formula shortages [\[source\]](#), to name a few. In each case, national stockpiles and existing market capacity were insufficient to cover supply shortages. But the US is not the only example. European countries have been suffering from similar problems in recent years [\[source; source\]](#).

An additional option that has been underexplored is the potential for governments to facilitate, incentivize, and otherwise leverage economic dynamism -- e.g. the rapid entry by de novo and existing firms into new product spaces to fill shortages in the current market. The policy options in this case are many -- including providing contracts and capital, reducing regulatory barriers and information asymmetries, to name just four. In this paper we leverage insights from the COVID-19 crisis across the U.S. and Europe to begin to unpack the role of government in incentivizing economic dynamism in times of crisis.

We refer to firm ability to rapidly ramp up, or rapidly pivot, production as manufacturing flexibility. Such flexibility might help ensure access to products critical to social well-being such as health or to national security during sudden shortages, but firm flexibility may also help nations stay at the forefront of technological advances and ensure access to products with national economic significance, such as general purpose technologies (Bresnahan, & Trajtenberg, 1995). Nations, through policy, can incentivize firm investments in flexibility.

Unfortunately, contemporary policy and market incentives under-incentivize firm investments in flexibility, deterring firms from maintaining the ability to successfully pivot production to address critical supply shortages caused by sudden natural, technological, or other shocks and crises. Firm level flexibility, while costly and difficult to develop, can benefit both firms (Teece, Pisano, and Shuen, 1997; Eisenhardt and Martin, 2000; Costa, et al., 2021), as well as nations and states (Kalathil, Morgan, Fuchs, 2021; Reynolds et al., 2021). We define a policy framework to specify the appropriate types of actions that local, regional, and federal actors

should take to effectively enable small, medium and large firms to quickly (and safely) pivot production and address shortages in supplies critical to population level health, security, or other measures of societal well-being (e.g. economic prosperity, equity, environmental well-being). Building on what we have observed in the industrial ecosystems of the United States, Spain, Portugal, the Netherlands, and Germany, we focus our attention on two main challenges that firms needed to overcome if they are to successfully pivot production during crises: firm entry into production, and firm market entry (and potentially, exit).

Under a crisis scenario, in most cases nations will ultimately rely on their domestic firms. Countries that have access to domestic manufacturers might be able to compel action during crises (such as through the US DPA). This strategy depends on the existence of a few, reliable manufacturers capable of scaling up production and either a strong domestic industrial base, or strong alliances, to allow these manufacturers to source (domestically or through allies) what cannot potentially be sourced through traditional channels due to global supply chain disruptions. However, research has shown, not all countries have access to sufficient, domestic industrial capacity to manufacture essential supplies (Breznitz, 2007; Amaral et al. 2023). One of the most widely used, and commonly discussed, policy tools to help nations respond to supply shortages during crises is stockpiling – where nations can use contracts to strategically support an industrial base (CRS, June 2020). However, stockpiled goods do not always provide immediate access to necessary supplies, and suffer from other opportunity costs ([Mason, 2011](#); [Huang et al., 2017](#); [Ajao, et al., 2015](#)). Alternatively, as firms redeploy resources and capabilities across related businesses in response to (and in the face of) environmental and market changes (Helfat and Peteraf, 2009; Helfat and Eisenhardt, 2004), countries may be able to rely on the entry of new firms into product spaces suffering with extreme shortages.

We argue that these pivots can be accomplished by incumbent firms of all sizes, as well as new entrants. Such pivots offer benefits in terms of additional capacity (especially in the service of small and non-mainstream markets) diversification of supply, and the introduction of new innovations and processes (Kalathil, Morgan, and Fuchs, 2021). The existing literature discusses how firm investments in flexibility benefits firms, such as through enabling entry into high-tech industries (Gaimon and Morton, 2005), as a source of competitive advantage (Teece, Pisano, and Shuen, 1997), and occasionally, as a “best-practice” (Eisenhardt and Martin, 2000). However, pivoting production can be costly and difficult to coordinate, involving potentially unreliable sources as well as long-lead time. Appropriate local, regional, and national policy can effectively reduce some of these barriers to pivoting production.

Existing literature on policy interventions to support firm flexibility focuses on adaptive regulation and “street-level bureaucrats” (Piore, 2011), as well as the role of government in supporting manufacturers, and the utilization of tools such as the Defense Production Act to respond to crises ([CRS, 2020](#)). Research on adaptive regulation discusses how governments can proactively create flexible regulatory systems (McCray, Oye and Petersen, 2010; Eichler et al., 2012; Bonnín Roca et al., 2017) with a goal of adapting to environmental changes such as changing technologies, industry structures, and sudden shocks. Crucially, these regulations must

respond to on-the ground realities (Piore and Schrank, 2018), while avoiding regulatory lock-ins that cement inappropriate features (Wilson, Freidmann, and Pollak, 2007). The literature on government support of manufacturers focuses on the government's role in facilitating and encouraging collaborative relationships between and among manufacturers to respond to new shocks, technologies, and organizational paradigms (Chiung-Wen and Chiang, 2001; Helper and MacDuffie, 1997). Here, government support can be especially helpful in facilitating learning and upgrading (McEvily and Marcus, 2005; Whitford and Zeitlin, 2004; Brandt and Whitford, 2017).

We propose a policy framework to support economic dynamism through manufacturing flexibility that makes use of the full suite of local and regional as well as national policy mechanisms, from acting as central repositories of information and validation, to contracts and procurements, through regulatory flexibility and street-level bureaucrats (such as NIST's Manufacturing Extension Partnership - MEP) to appropriately incentivize both pre-crisis and during crises investments in flexibility among firms of all sizes, taking advantage of the specific strengths and weaknesses of firms of different sizes. We argue that specific national and federal support for firms should be focused on working with large multi-businesses firms that are particularly capable of redeploying resources across locations & products (Lieberman, Lee, and Folta; 2017, Bernard et al., 2010). Policy at this national level should also focus on creating and acting as a central repository of information and validation, while pursuing regulatory flexibility to quickly process and certify new entrants. Federal procurements and contracts can be used to expand the supply and availability of key intermediate inputs, while also guaranteeing markets for the end product when used in coordination with mandates (such as Germany's N95 mandate) and agency rule announcements (e.g. OSHA and CDC guidance on mask usage in the workplace). Conversely, local and regional policy may be best suited to identify small and medium enterprises, accelerate collaboration, and support rapid network formation (Whitford, 2011; Brandt and Whitford, 2018; Helper and Stanley, 2007).

To inform the construction of this framework, we draw on a mix of both quantitative and qualitative data from firms pivoting their production to enter the surgical mask, respirator, and mechanical ventilator markets in the US as well as several countries in Europe. We draw on over 150 interviews with manufacturers, regulators, purchasers, as well as other external actors and industry observers; and our quantitative data covers supplier listings, regulatory approvals, and government contracts.

1. Methods

We perform a five country case-study (Yin, 2009; Wonglimpiyarat, 2016) to unpack the different policies implemented by Germany, Portugal, Spain, the Netherlands, and the United States of America to help domestic firms increase or pivot their production of medical supplies and equipments during COVID-19. Here, we triangulate data (Jick, 1979) from industrial data sources, regulatory approvals, government contracts, archival data (news articles about

companies and states, state and company websites), and 154 qualitative interviews to understand the different industrial contexts of surgical masks, respirators, and mechanical ventilators in Germany, Portugal, Spain, the Netherlands, and the United States of America. We have interviewed healthcare workers, regulators, non-profit organizations, and research centers, as well as experts from industry to gain insight into the experiences of firms who pivoted or increased their production, the processes by which they did it, as well as those of the external actors (states, non-profits, corporate partners, etc.) who interacted with these firms.

2. COVID-specific Findings

Our sample consists of both SMEs and large producers of masks, respirators, meltblown fabric, and mechanical ventilators. Interviewed smaller firms commonly reported difficulty in accessing information on how to make medical grade masks and mechanical ventilators. On the one hand, SMEs producing masks faced major hurdles in access to machines, including quality issues, shipping delays or costs, lack of assembly and run knowledge, and shortages in maintenance supplies. On the other hand, SMEs pivoting their production to mechanical ventilators experienced serious shortages of medically approved components, in particular, Positive end-expiratory Pressure (PEEP) valves and sensors. While there was an effort by the majority of SMEs in our sample to source mechanical ventilator components domestically, most of them ended up relying on China to supply such components. Similarly, most SMEs producing medical grade masks relied as well on China to deliver the necessary machines. However, the quality of these materials was highly heterogeneous, requiring creative problem solving and engineering to operationalize. One mask manufacturing start-up described spending a month of 10 hour days figuring out every nuance of a machine purchased through AliBaba that had *“probably been sitting in the corner for 10 years.”*

Larger manufacturers in the United States, as they reported it, had few of these challenges. Companies such as Honeywell and GM were able to rely on in-house capabilities or existing suppliers to custom manufacturer machines to make surgical masks and respirators, and were fully operational within three weeks. These larger companies were also able to quickly obtain regulatory approval for new products that they launched. However, some of these larger manufacturers, especially large manufacturers of end-products, described difficulties with the DPA. Some of these companies pivoted to manufacturer medical supply products without any government request or help, and when the DPA was applied, they found themselves unable to fulfill some of their existing contracts (due to prioritization of the DPA contracts) as well as some negative PR, as it appeared that the companies were unwilling to help until the government forced them to. A similar example was witnessed with the large manufacturers pivoting to producing mechanical ventilators. However, we interviewed an incumbent manufacturer of mechanical ventilators in the US that managed to leverage the DPA to force its domestic suppliers to prioritize their orders without the increment in price observed in the market due to the supply chain disruptions triggered by COVID-19.

In countries with strong medical device industrial bases like Germany and the United States, the Government focused on putting out large contracts to guarantee a large enough market to justify firms in ramping-up production. While Germany did not necessarily implement a policy tool such as the United States' DPA, due to the geographic location of these domestic manufacturers and, as reported, "*shorter lead times to the customer*", domestic manufacturers appear to have prioritized large government contracts. In both Germany and the US, due to the full reliance of the Government and other policy making institutions on existing large manufacturers, smaller firms had a rougher time entering the market. In fact, Germany is the only country in our pool of five countries to not implement any emergency use authorization, therefore denying new firms pathways to quickly pivot production in response to the crisis outside of the slow, established market entry regulatory process.

In our sample, small and medium firms attempting pivots did best in cases where the state government had knowledge about firm capabilities, and served to augment firm investments through, for example, state assistance helping the company expand their product lines in Alabama and Missouri. In other cases, such as in Spain, the state had a direct impact in helping a manufacturer to source components that were in shortage in Europe and were crucial for this manufacturer's production pivot. Our research suggests firms did less well, especially in terms of speed, when they were reliant on state-provided capital to start production, as seen in New York State and Portugal, where firms were delayed multiple months while waiting for funds to come through. However, it is unclear the degree to which higher-quality state support would have improved outcomes for these firms, or if these firms were less qualified or less-willing contributors.

Countries and state governments also varied in the extent to which they were able to coordinate across regions. On the one hand, states like Alabama ran operations through the state department of commerce, but used regional economic development actors and universities to identify and interface with local manufacturers. Similarly, the Netherlands relied on a public-private partnership to coordinate with its Ministry of health procurement contracts and on its regulatory institutions to help manufacturers pivot their production. On the other hand, while Germany had a centralized mechanical ventilator procurement, each of its Federal states was also in charge of coordinating internal production for regional supply of medical devices and masks. A more extreme example of this was witnessed in the state of New York where each of its five regions pursued an independent approach to supporting manufacturers, without an explicit state-driven plan, and with the result of firms often not knowing who was responsible for what.

3. Discussion and Policy Implications

The entry process through which firms have to navigate in order to enter a new market is usually fraught with barriers (Bain, 1956; Demsetz, 1982; Agarwal & Gort, 1996). Lowering such barriers smooths this entry process making it easier for new entrants to exploit an entry opportunity (that can emerge, for example, from a crisis). To secure access to critical products in

times of crisis, it is in a country's interest to facilitate such entry if incumbent firms are not able to alone fulfill the demand. To date, it is still unclear which combination of the variety of policy mechanisms that countries have available are the most appropriate to address specific supply shortages. Building on the observation that, in times of crisis, firms pivot their production into product spaces experiencing shortages, our research suggests that policy can accelerate the timeline and effectiveness of firm pivots (from new entrants as well as firms of all sizes) during crises.

Our paper unpacks the actions that different types of institutional actors can take to enable domestic firms to quickly (and safely) pivot production in times of a global supply chain shortage. Building on what we have observed in the industrial ecosystems of the United States, Spain, Portugal, the Netherlands, and Germany, we focus our attention on two main challenges that such firms need to overcome to successfully pivot production during crises: firm entry into production, and firm market entry. We hypothesize that the outcome, as well as the likelihood, of a firm successfully pivoting production into a product space experiencing extreme shortages is dependent on the firm's expected cost of pivoting production, weighed against the expected benefit, all relative to other products that the firm could be producing. As such, we propose a policy framework intended to either reduce the burden of, or increase the rewards from, the decision to pivot to produce a specific product. This product-specific framework is explicitly designed to address extreme supply shortages in specific products, and may not be directly applicable to other national interests, such as promoting innovation or technological progress.

The effectiveness of this framework may vary with the existence of firms or founders with sufficient tacit or technical knowledge to pivot into a given product area. However, our research points out that such knowledge might only be crucial for more technologically advanced products (such as ventilators, relative to masks/respirators). While we observed firms with relevant capabilities and competencies (such as highly automated manufacturing and experience with distributors) that were able to pivot faster and were most successfully (in terms of regulatory approval), we also witnessed garbage collectors, pilots, and patent lawyers that were all able to successfully stand up mask/respirator manufacturing sites. Conversely, for the case of mechanical ventilators, only firms who partnered with research centers, medical doctors, or larger firms, were able to have the knowledge and capabilities to successfully enter the market.

At each level, we consider separate policies for small and medium sized firms, relative to large firms. Figure 1 illustrates how different actors (National/Federal to Regional/Local) implement different policies depending on the size of the pivoting firms. We suggest that the national and federal governments should form partnerships with large firms and create contracts to satisfy the most obvious and pressing buckets of need (as the US and Germany governments did through partnerships with major medical distributors and manufacturers to get access to PPE and mechanical ventilators), while pursuing blanket policies that reduce the burden and increase the benefit of pivoting for firms attempting to pivot production, and specifically supporting small and medium sized firms through investments in regional programs (such as the EDA and NIST MEP in the US or the Compete2020 in Portugal). We propose that local, regional, and state

governments, on the other hand, should seek to provide more targeted aid to small and medium enterprises that *are already seeking to* pivot production of their own accord, seeking to upgrade their capabilities and help individual entrants find partners and collaborate based on their specific needs. Finally, national and federal governments can implement a set of policies transversally to all firms such as central repository of information (for product designs, trusted equipment vendors, regulatory consultants), fast track regulatory approvals (to facilitate market entry), or establishing national mandates to guarantee the existence of a market to firms deciding to pivot.

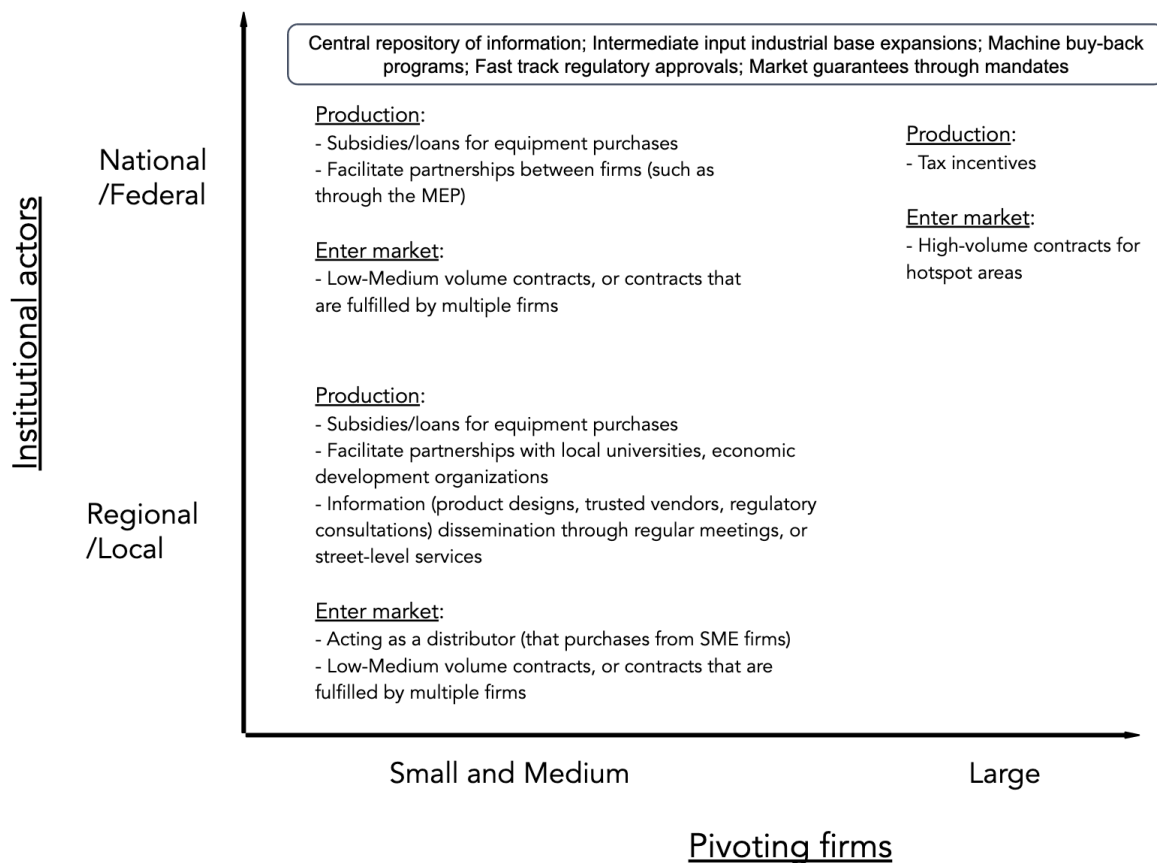


Figure 1: Product-specific framework for policies to reduce burden and increase reward of production pivot by domestic firms in times of crisis.

The framework provided in Figure 1 allows countries to plan crisis strategies at different levels. As it has been observed over the past decade, in times of crisis, federal and national governments are expected to implement nation-wide policies to coordinate activities across both organizations (Ishiwatari, 2021) and sectors (Nolte, Martin, Boenigk, 2012). However, during the COVID-19 crisis, national governments focused almost exclusively on large manufacturers, at the expense of implementing low-hanging mechanisms (such as central repositories of

information) that could have significantly benefited both SME manufacturers, as well as state, regional and local institutions. Conversely, such institutions were left to their own devices during the pandemic (([Hale et al., 2020](#)), and each state pursued its own strategy to support manufacturers. While such experimentation has advantages (Singerman, 2020; Morgan, 2017, Manski, 2013; [Romano, 2006](#)), state responses to supporting manufacturers were highly uneven.

The proposed framework is intended to provide countries with a new perspective on how to leverage the whole range of domestic firms in response to a crisis, instead of solely relying on large manufacturers. Understanding that regional and local institutional actors have a role to play in facilitating SMEs to pivot their production and enter new markets might allow countries to exploit their internal industry while supplying underserved markets.

4. Conclusion

Firm-level investments in flexibility and dynamic capabilities are both costly, and difficult to implement correctly. When firms pivot production and are unable to break into sufficiently sized markets, they may be deterred from pivoting production to address future crises¹. As such, nations have an added incentive to assist firms that pivot production during crises to address national needs. In this paper, we present a policy framework for incentivizing manufacturing flexibility during crises to respond to extreme shortages, where different institutional actors are assigned roles designed to support firms of different sizes. The intended goal of the proposed framework is to increase both the total number of firms that pivot production to serve product spaces experiencing extreme shortages, as well as the effectiveness of firms of *all* sizes in addressing said shortages.

While the above framework is designed to guide policy decisions during crises, policy can also increase firm investments in flexibility before crises. Both our research, as well as existing research (Zollo and Winter, 2002), suggests that dynamic capabilities are learned and developed over time, and are best among those who actively cultivate them. Indeed, some of the fastest pivoters in our sample were firms that had explicitly invested in flexibility, such as Advoque Medical. As such, incentivizing non-crisis investments in flexibility may have high returns in incentivizing pivots during crises. Current approaches to supply chain resilience overlook the ability of firms to rapidly pivot to respond to sudden shocks, and also underestimate the role of design and/or innovation to enhance flexibility and resiliency. Policymakers have suites of tools, such as common standards and public-private partnerships that they can utilize to incentivize firms to invest in flexibility during non-crisis situations, to prepare for an increasingly uncertain future. To best prepare for future shocks of unknown scale and scope, nations must begin investing in building a flexible manufacturing base.

¹https://www.washingtonpost.com/investigations/in-the-early-days-of-the-pandemic-the-us-government-turned-down-an-offer-to-manufacture-millions-of-n95-masks-in-america/2020/05/09/f76a821e-908a-11ea-a9c0-73b93422d691_story.html

5. Annex

Appendix A: Background on medical supplies prior to COVID-19

Before the pandemic, surgical masks were almost exclusively used in the medical market. In 2019, the monthly market for surgical masks was 108-140 million masks, with US suppliers producing 17 million (15% of US market) surgical masks per month, and imports providing an estimated 85% of the US market. In contrast, when it comes to mechanical ventilators, both the US and Europe own nine out of the Top 10 largest firms of the world market (BCC report).

Product standards for surgical masks and respirators remained unchanged during the COVID-19 pandemic. NIOSH did not substantially change their review process, and continued their review that focused heavily on production and process. In contrast, for surgical masks and mechanical ventilators, the United States and several European countries implemented numerous changes to the regulatory approval process. These temporary regulatory changes lowered the bar for new entrants to pivot their production and address these countries' domestic shortages for mechanical ventilators and surgical masks.

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Initial idea

1) policies that help companies set up production National and Trans-national policy for domestic manufacturing flexibility: From

- Value of firm flexibility for 1) innovation, 2) crisis, 3) ?? equity? Security?
 - Liz reynolds paper
 - Dosi papers <- (2021/2022 - covid stuff)
 - Dan gross
 - Our work
- Firms underinvest in flexibility because it is costly and risky to invest in
- Firms that successfully invest in flexibility tend to perform better in the long run
- Policy currently under-incentivizes flexibility
 - Regulatory barriers
 - Contracting barriers
 - Role of distributors
- What policies can increase firm investments in flexibility?
 - Two mechanisms:
 - Reduce cost of switching (including market entry) -> increasing firm capabilities?
 - Increase rewards from switching
 - Tools:
 - Adaptive regulation, central repositories, regional facilitators, procurement contracts, grants, subsidies, competitions, industrial base expansion investments
 - How to choose the appropriate mix between stockpiling and pivoting as a function of different product/device attributes.
 - How to cover the incremental costs of maintaining the slack, or to maintain capabilities that are only modestly used, that may be need to facilitate pivoting
 - How to incentivize innovation, standards, and design for flexibility

The role of adaptive regulation

- Address clearly identified industrial innovation policy challenges
- Draw upon several disciplines highlighting novel theoretical and/or practical insights
- Articulate how the insights might be operationalised in practical policymaking
- Provide illustrative examples from practice where appropriate

How to figure out which among a large number of potential hazards/challenges that could arise, it is important to prepare for.

- How to choose the appropriate mix between stockpiling and pivoting as a function of different product/device attributes.
- How to cover the incremental costs of maintaining the slack, or to maintain capabilities that are only modestly used, that may be need to facilitate pivoting (i.e. the general resilience vs efficiency tradeoff)

A fourth set of issues, which you do talk about in the present paper, are the need to maintain an ability to quickly put folks together (build networks), relax or modify regulatory barriers, rapidly share information, train people on technical or regulator issues, etc.

P.S. I have been thinking a lot recently about how current supply chain approaches to resilience overlook

1) economic dynamism (e.g. the ability for firms to pivot)

2) the role for design and/or innovation to enhance flexibility / resiliency / etc.